

REMARKS

Applicants draw the Examiner's attention to a typographical error that appears in the Specification at page 8, lines 3-5. Here, the sentence reads, "Alternatively the C₃₋₆ or C₃₋₇ cyclopropyl may be spiro-bound to the adjacent carbon without an intervening C₁₋₇ alkyl." It is clear that "cycloalkyl" (with 3-6 or 3-7 C atoms), not "cyclopropyl" was intended as can be seen from the reference to "cycloalkyl" in the Specification on page 8, line 1.

Claim 1 has been amended to correct improper punctuation and to better define the terms "alkyl," "cycloalkyl" and "aralkyl," which are used in a non-IUPAC manner. Support for these amendments can be found in the Specification on pages 5-7.

Claims 14, 15 and 39 have been canceled.

Applicants have introduced seven new claims. Claim 42 is a dependent claim that recites the preferred Wittig Chemistry that was deleted from claim 40. Support for new claims 43, 44, 47 and 48 can be found in claims 1 and 16.

Support for new claims 45 and 48 can be found in the Specification on page 8, lines 1-3.

No new matter has been added.

Rejections Under 35 USC § 112, second paragraph

The Examiner has rejected claims 1, 2, 5-10 and 13-15 as being indefinite. The Examiner points out that in line 8 of claim 1, the punctuation leads to unintended claim interpretation. The Examiner suggests amending the claim by deleting the comma after the

variable "X" and replacing the comma after "NH" with a semi-colon. Applicants have made these corrections, thereby obviating the rejection.

The Examiner has rejected claims 13, 15 and 39 as being indefinite, contending that the Specification does not set forth any steps involved in determining how to identify which patients need "inhibiting the cysteine protease Cathepsin S." The Examiner contends that it is unclear what diseases and treatments the claim is intended to encompass and contends that without clinical research to identify the patients and diseases intended to be treated, a skilled physician would be unable to determine what was claimed. Applicants respectfully traverse.

Applicants respectfully submit that the Examiner is confused. The claims are directed to "a method of inhibiting the cysteine protease Cathepsin S..." and not to treatment of particular diseases. Applicants, however, have canceled claims 14, 15 and 39 in order to expedite prosecution, but reserve the right to submit these claims in a divisional application.

The Examiner has rejected claim 40 as being indefinite for recitation of the phrase "for example..." Applicants have amended claim 40 removing the example and introducing it into a new dependent claim.

Rejections Under 35 USC § 112, first paragraph

The Examiner has rejected claims 14, 15 and 39 for lack of enablement. The Examiner again contends that the Specification does not enable any skilled physician to make the invention commensurate in scope with these claims. The Examiner indicates that

"the how to make requirement" of the enablement requirement, when applied to process claims refers to carrying out the claimed process.

The Examiner also contends that undue experimentation would be needed in order to determine suitable dosages and whether or not "a number of fundamentally different Cathepsin S related diseases" would be correlated to clinical efficacy of treatment. The Examiner further indicates that the Specification recommends a 10,000-fold range of dosage. Applicants respectfully traverse.

Applicants respectfully point out that the Examiner appears to be confused as to the requirements for method claims directed to the use of a particular product. However, as Applicants have canceled claims 14, 15 and 39, this rejection is moot.

The Examiner has rejected claims 14, 15 and 39 for lack of utility. The Examiner refers to specific references which he contends established that in 1999 no diseases were known to be treatable by inhibitors of Cathepsin S. The Examiner also contends that Saegusa shows that even by 2002 no clinical uses of such inhibitors were recognized. Applicants respectfully traverse.

By allowing the compound claims, the Examiner has acknowledged a utility for the compounds. As a consequence, it doesn't seem to make sense that there is no utility for a use of the compound. However, in order to expedite prosecution, Applicants have canceled claims 14, 15 and 39 thereby obviating the rejection.

Allowable Subject Matter

The Examiner has indicated that claims 12, 16-38 and 41 are allowed in addition, the Examiner indicates that claims 1, 2, 5-10 and 13 are allowable if amended to overcome the rejections under 35 USC § 112, second paragraph. Lastly, the Examiner indicates that claims 3, 4 and 11 would be allowable if rewritten in independent form or if the base claim upon which they depend were allowable.

Applicants have amended claims 1, 2, 5-10 and 13 to overcome the rejections under 35 USC § 112, second paragraph. As a consequence, claims 3, 4 and 11 are no longer dependent upon a rejected base claim and are also allowable.

In view of the above remarks, all of the claims remaining in the case are submitted as defining non-obvious, patentable subject matter.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of \$950.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.



Appl. No. 10/015,186

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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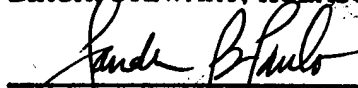
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Attachment(s)

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: 02-27-2004
(Date of Deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP


(Signature)
February 27, 2004
(Date of Signature)